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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,509	03/16/2004	Riqiang Yan	29915/00281C	4081

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EXAMINER

LUNDGREN, JEFFREY S

ART UNIT PAPER NUMBER

1639

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/801,509	<b>Applicant(s)</b> YAN ET AL.	
	<b>Examiner</b> Jeffrey S. Lundgren	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-6,14-28,36,38,41,43,49,52,58-60,63,64,66,70 and 72-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,4-6,14-28,36,38,41,43,49,52,58-60,63,64,66,70 and 72-83 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 4-6, 14-28, 70 and 72-83, are drawn to compositions comprising isolated polypeptides having the general formula  $P_3P_2P_1-P_1'P_2'P_3'$ , classified in class 530, subclass 300.
- II. Claims 36, 38, 41 and 52, are drawn to a polynucleotide, vector, host cell, and method of expressing a polypeptide in a host cell, classified in class 435, subclass 420.1.
- III. Claims 43, 49, 58-60, 63, 64 and 66, are drawn to methods of assaying the activity of proteins in the presence of peptides having the general formula  $P_3P_2P_1-P_1'P_2'P_3'$ , classified in class 436, subclass 86.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different compositions, restriction is deemed proper because the composition claims as presented constitute patently distinct inventions. Specifically, the inventions as defined above are physically and/or functionally distinct, wherein the practice of one invention does not require the other. Although compositions comprising the polypeptide of Group I are related to the polynucleotide, vector and host cell of Group II by the peptide sequence, the compositions of each group are chemically distinguishable, have unique functions, and different uses (*e.g.*, an amino acid as in Group I can be used to generate a group of antibodies in AD-related diagnostic methods and can be prepared synthetically, whereas the polynucleotide, vector, and host cell of Group II each require the chemical composition of polynucleotides and their function for protein expression).

Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the invention of Group I may be used in a method of raising

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AD-diagnostic antibodies, or a method of identifying mutant secretase proteins with various levels of activity.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because the method claims as presented constitute patently distinct inventions. Specifically, the inventions as defined above are physically and/or functionally distinct, wherein the practice of one invention does not require the other. Although methods for expressing a given peptide and using the same peptide are related by the peptide, the individual steps are not the same, and each require the use of different reagents/components (e.g., a host cell as in Group II versus a  $\beta$ -secretase as in Group III).

For these reasons, Groups I-III are considered distinct inventions.

Further, a search and examination of more than one of the methods as claimed in one patent application would result in an undue burden on the Office. The searches required for the examination of any two groups are not co-extensive, the classifications are different, and the subject matter between group is largely divergent. For example, the peptides of Group I may be prepared synthetically, may be identified independent of a nucleic acid which may encode the polypeptide, and therefore have a search that is substantially different than that of the search required for Group II. Further, the alternative methods of using the peptides of Group I as identified above relate to the antibody art, whereas the method of Group III relates to a search of the art directed to enzyme cleavage assays. Finally, a search of the polynucleotides and methods of using the same, as in Group II, is substantially different than the search for a method directed to an assay using a polypeptide that requires a secretase.

Accordingly, restriction of the groups as defined above is deemed proper.

### *Election of Species*

This application contains claims directed to the following patentably distinct species of the claimed invention:

- A. *a single  $P_3P_2P_1-P_1'P_2'P_3'$  sequence* – No matter which group Applicants should elect, Applicants are required to elect a single peptide sequence

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comprising the P<sub>3</sub>P<sub>2</sub>P<sub>1</sub>-P<sub>1</sub>'P<sub>2</sub>'P<sub>3</sub>' sequence. Applicants should identify the specific amino acids corresponding to each of the P values, and select a single SEQ ID NO corresponding to the elected P<sub>3</sub>P<sub>2</sub>P<sub>1</sub>-P<sub>1</sub>'P<sub>2</sub>'P<sub>3</sub>' sequence, if provided. Applicants should also identify a single polynucleotide sequence by SEQ ID NO that corresponds to the elected P<sub>3</sub>P<sub>2</sub>P<sub>1</sub>-P<sub>1</sub>'P<sub>2</sub>'P<sub>3</sub>' sequence; and

- B. *a single aspartyl protease* – No matter which group Applicants should elect, Applicants are required to elect a single aspartyl protease, and identify the elected protease by SEQ ID NO.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

*Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.* An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

#### ***Consideration of Rejoinder***

The Examiner has required restriction between product and process claims. Where Applicants elect claims directed to the product, and a product claim is subsequently found

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allowable, withdrawn process claims that depend from or otherwise **include all the limitations of the allowable product claim** will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR § 1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

#### ***Correction of Inventorship***

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Time for Reply***

Applicant is reminded that 1-month (not less than 30 days) shortened statutory period will be set for reply when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program. M.P.E.P. § 809.02(a).

***Conclusions***

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsius verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSL

Jon Epperson  
